19652

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D.C. 20548

HR1-BILL-17
B-204277

October 6, 1981

The Honorable Richard G. Lugar
United States Senate

Dear Senator Lugar:

As requested, we have reviewed S. 1442, entitled "Food Safety Amendments of 1981," which is intended to revise and update the Nation's food safety laws. The Amendments are aimed at improving food safety decisions by providing for (1) an assessment of health risks presented by food substances, (2) referral of food safety questions to expert scientific advisory panels and (3) authority for a flexible regulatory response based on the risks and uses associated with a substance.

In response to a request from seven Members of Congress, we have substantially completed a review of issues relating to the Delaney Clause and alternatives to regulating food additives which may cause cancer.

Our work, which began in April 1980, involved reviewing legislation, legislative histories, literature, and reports on the regulation of cancer-causing substances. We obtained information from representatives of the Food and Drug Administration (FDA), Environmental Protection Agency, Occupational Safety and Health Administration, and Consumer Product Safety Commission. In addition, we interviewed food safety experts, including 5 former FDA Commissioners and 4 former General Counsels, 11 biomedical researchers, and representatives from 3 biomedical research organizations, 6 consumer groups, 15 food and chemical companies, and 5 trade associations.

On June 23, 1981, we testified before the Subcommittee on Department Operations, Research, and Foreign Agriculture, House Committee on Agriculture, on FDA's regulation of cancer-causing substances and the Delaney Clause. As a result of our work, we concluded that the Congress should examine the continued appropriateness of the Delaney Clause because of (1) advances in the

018766

ability of analytical detection methods to identify substances at very low levels, (2) uncertainties about the human risk from low levels of carcinogens, and (3) the inflexibility that exists under current law. A copy of our testimony is enclosed for your information. We are presently drafting a report to the Congress on the regulation of cancer-causing food additives and will send you a copy when it is issued.

During our testimony we noted that there are no simple solutions to determine whether a substance causes cancer. Each step in testing a substance--tests and risk assessment--involves uncertainty. Scientific methods and analysis do not always yield a single incontrovertible answer. The cause of cancer and the amount of a substance needed to initiate carcinogenesis remains unknown. Expansion of scientific knowledge to allow researchers to determine whether there is a safe level of a carcinogen remains a challenge for the future.

The following comments relate to specific sections of S. 1442 and are based primarily on our interviews with food safety experts and Government officials and our review of recent studies dealing with the Delaney Clause.

Section 107 would permit withdrawal of the use of a previously approved food additive over a period of time when the continued use of the substance would not present an imminent public health danger. In 1979 FDA's and the Department of Agriculture's attempt to phase out the use of nitrite was overruled by the Department of Justice. On March 30, 1979, the Attorney General replied to inquiries about the proposed phaseout. He stated that the Congress had not granted these agencies authority to phase out a carcinogen's use and that, if nitrite is, in fact, a carcinogen, the decision to postpone or eliminate a ban must rest with the Congress. It therefore appears that authority for the gradual elimination of a substance would eliminate a deficiency in the current law.

Section 112(e) of the bill would require the Secretary of Health and Human Services (HHS) to consider human risk assessment under actual conditions of use. Included in this assessment would be such factors as epidemiologic and metabolic data and distinctions between primary and secondary carcinogens. Experts that we interviewed generally believed risk assessment

is an exercise that is not yet sufficiently developed to be used as a primary basis for regulating human exposure to carcinogens. Potential errors in this process could significantly underestimate the actual human risk from exposure. For example, the National Academy of Sciences gathered risk estimates on the use of saccharin. These estimates predicted between 0.22 and 1,144,000 cases of bladder cancer over the next 70 to 80 years based on the same data. Epidemiologic and metabolic data for food additives are often unavailable, and their usefulness in the regulatory decision process is questionable.

Finally, the director of FDA's Bureau of Foods has stated that an attempt to distinguish between primary and secondary carcinogens is not currently feasible. Testing methods do not provide for identifying different types of carcinogens. Most of the experts did not believe that any distinction among types of carcinogens should be a part of regulatory policy.

Section 112(f) of the bill would retain the Delaney Clause but with important changes. Substances with low potency and exposure would not be covered by the clause. Also, the bill provides that, for the Delaney Clause to apply, the food additive must be shown to be a significant human risk. If a food additive found to be carcinogenic has (1) a substantial history of use and (2) no practical substitute, the Secretary of HHS will consider a number of factors in deciding whether or not it may be used. These include risk and the nature and extent of consequences resulting from limitations and prohibition from the use of an additive, including effects on nutritional value, consumer cost, and the availability and acceptability of food. Our interviews showed that little or no data exist on economic, nutritional, and esthetic factors. Consequently, new data would have to be gathered, and some form of retrieval system would be required.

Section 112(f) would provide that the Secretary of HHS could consider the feasibility and effect of providing information to consumers concerning the type and extent of risks associated with the additive as a basis for informed choice by consumers. A consensus emerged among food safety experts we interviewed. They asserted that labeling was ineffective. In addition, a recent study noted that a large portion of the population is functionally illiterate. Many consumers are too young to read or to understand the information provided. Restaurants

and institutions, which provide no labeling information, serve a large part of the populace. Also, studies on cigarette labeling show that labels become less effective with increased use. However, a public education program when combined with labeling was thought to be useful as a supplementary tool, especially for the benefit of high-risk groups.

Section 117 assumes that substances which have been classified as Generally Recognized As Safe (GRAS) will remain in the food supply. Similarly, section 119 assumes that a food contact substance may be either GRAS or a prior sanction substance.

Use of both categories is based upon experience drawn from common use in food. Several Government and private organizations have recognized that a history of safe use is not an adequate basis for determining a substance's safety. We have recommended that the Congress amend the Federal Food, Drug and Cosmetic Act to eliminate safety testing exemptions for GRAS and prior sanction substances. ("Need for More Effective Regulation of Direct Additives to Food" HRD-80-90, Aug. 14, 1980.) A copy of our report is enclosed for your information. We have also recommended that the proposed amendment provide a date on which the safety of all GRAS and prior sanction substances must be subject to Federal review and approval.

Section 106 would redefine indirect additives as food contact substances, and section 119 would provide that a food contact substance may be used without notification if its constituents are not reasonably expected to become a component of food under its intended condition of use. A manufacturer must submit a premarket notification statement, including summary data which show that the substance does not present a significant risk to the public health. If FDA finds the manufacturer's supporting data inadequate or finds a significant risk to the public health, it must act within 90 days to stay the use of a substance. Advances in analytical methods for detecting chemical residues have revealed that extremely minute amounts of indirect additives may migrate into food. Food packaging materials were never intended to become part of food. Many are toxic and some are probably carcinogenic. Because these substances are present in food in such minute quantities, their effect upon human health is unknown. Although many food contact substances individually may pose an insignificant risk, their combined additive and/or synergistic effect may expose the public to a greater health hazard than any individual substance. Further, assessment procedures to estimate the risk from these substances may be inadequate to the task.

Section 131 essentially repeats the food additive provisions for color additives, including use of risk assessment techniques, if desired, to determine the nature and extent of risk and use of economic and nutritional factors when significant risk is found. Color additives offer no nutritional benefits; they provide only esthetic appeal. One former FDA Commissioner we interviewed commented that he was unwilling to accept any carcinogenic risk from a color additive in exchange for an esthetic benefit. He believed that risk should be the only factor considered when deciding whether or not to permit use of a color additive.

The proposed legislation deals with many other areas of the Federal Food, Drug and Cosmetic Act. Our recent work dealt only with the Delaney Clause and carcinogenesis research. Consequently, we have limited our comments to the aspects of S. 1442 which are covered in our draft report.

We hope these comments will be useful to you in considering the proposed legislation. Similar comments are being forwarded to Senator Orrin G. Hatch, who also requested our comments on S. 1442.

Sincerely yours,

Milton J. Socolar

Acting Comptroller General
of the United States

Enclosures - 2